IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Michael G. Orchard et al.	Examiner:	John Mabry
Serial No.:	10/560,385	Group Art Unit:	1625
Filed:	January 12, 2007	Docket No.:	AC-51-US
Title:	PIPERIDINE AS GCS INHIBITORS	Confirmation No.:	3846

Response to Restriction Requirement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Pursuant to 37 C.F.R. §1.143, Applicants respond to the Restriction Requirement mailed December 30, 2009. The examiner issued a restriction as follows:

> Group I, claims 1-4, 6 and 23, drawn to a compound of Formula I, a pharmaceutical composition comprising such compound, and the intermediate compound of Formula III.
>
> Group II, claim 7, drawn to a process of preparing a compound of Formula I.[1]
>
> Group III, claims 24-38, drawn to method of inhibiting and treating a disease or condition as claimed comprising administering an effective amount of the compound of Formula I.

The Examiner argued that these claims do not relate to a single general inventive concept under PCT Rule 13.1 and 13.2. In particular, the Examiner alleged that the special technical feature is found in EP 0536404 as described by Ezure et al. (Example No. 8 on page 10 and examples 12, 14, 15, 18 and 22) and therefore is not a contribution over the art.

[1] The Examiner noted that claim 7 is directed to a process of preparing compounds and pharmaceutical compositions of Formulae I and III. Applicants respectfully note that claim 7 is directed to a process of preparing a compound as defined in claim 1, which process comprises reacting an intermediate compound of formula II with R^2CHO along with other reagents or deprotecting an intermediate compound of formula III. Therefore, claim 7 is linked to the general inventive concept of the compound of Formula I.

Applicants respectfully disagree. Examples 8, 12, 14, 18, 18 and 22 of EP 0536402 cited by the Examiner all disclose the synthesis of deoxygalactostatin type compounds, which are (2R,3S,4R,5S)-2-Hydroxymethyl-3,4,5-piperidinetriol compounds, which compounds all have a different stereo configuration from the claimed Formula I (2S, 3R, 4R, 5S) and therefore is not anticipatory art. Because the compounds of Formula I are novel and that such compounds link the inventions to a single general inventive concept, the restriction on the compounds/pharmaceutical composition/intermediate of such compound claims and the method of use of such compounds is improper. In addition, the MPEP provides that:

> The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product . . .
>
> A process is specially adapted for the manufacture of a product if it inherently results in the product and an apparatus or means is specifically designed for carrying out a process if the contribution over the prior art of the apparatus or means corresponds to the contribution the process makes over the prior art.

MPEP 1850. As claim 7 is directed to a process of preparing the compound of Formula I (please see footnote above), restrictions of claim 7 is also improper. Applicants earnestly request reconsideration of the restriction requirement.

In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right to reinstatement or rejoinder in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected inventions in divisional applications, Applicants provisionally restrict, with traverse, to Group I, claims 1-4, 6 and 23 and elect a compound as disclosed in Example 1 of the specification as a single species for search purposes. Applicants provisionally withdraw the remaining claims.

Reconsideration and withdrawal of the Restriction Requirement and a speedy allowance of the claims submitted is respectfully requested. The Examiner is invited to contact the undersigned by telephone in the event of any questions.

As this response is filed within one month from the date of the mailing of the restriction requirement, it is believed this response is timely and no fees are required. If this is not correct, however, please charge any additional fees, or credit any overpayment, to Deposit Account No. 50-4255

Respectfully submitted,

Dated: February 1, 2010

By /Brittany La/
Brittany La
Reg. No. 58,337

HOXIE & ASSOCIATES L.L.C.
75 Main Street, Suite 301
Millburn, NJ 07041
(973) 912-5232